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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/190,138	11/12/1998	H. WILLIAM BOSCH	029318/0109	6300

7590 12/24/2002

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EXAMINER	
WARE, TODD	

ART UNIT	PAPER NUMBER
1615	27

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/190,138	BOSCH ET AL.	
	Examin r	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE f this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-36,40-45,47-49 and 51-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-36,40-45,47-49 and 51-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of request for extension of time (granted) and notice of appeal both filed 8-12-02 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7-11-02 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 11-34, 40-41, 44-45, 47-48, 51-62, 69-96, 111-119 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309).

'309 teaches aerosol particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The surface modifiers can be found at column 7, lines 55-63 and in the examples and are the same as those of the instant application as stated on page 26, line 10-page 27, line 28. '309 also discloses the spray-drying and freeze-drying the compositions. Example 14 discloses that the concentration of drug is within the instant ranges (i.e. 200 μg/5mg albuterol is equivalent to 40 mg/g). The compositions of the instant claims and those of '309 do not appear to be different. Both are aerosol compositions comprising spray- or freeze-dried drug particles less than about 100 μm, and deliver an agent to the deep lung (C 9, L 59-63). Furthermore, '309 teaches that varying the spray drying parameters, the aerodynamic properties of the inhaled particles can be effectively controlled through, for example, adjusting the inlet temperature or the feed rate and pressure of the compressed air to alter particle size (C 27, L 12-31) resulting in particle sizes that provide optimal deposition within targeted sites within the respiratory tract.

4. Claims 11-34, 40-45, 47-48, 51-62, 65-96, and 97-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309) in view of Liversidge et al (5,145,684; hereafter '684).

'309 is relied upon for all that it teaches as stated previously.

'684 teaches particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The particles of '684 are for administration of drugs such as corticosteroids (known for treatment of asthma and

allergies by administration in metered dose inhalers) and are produced by milling under non-pressurized conditions. After milling, the particles are separated from the milling dispersion. This appears to result in particles that are the same as those of the instant claims, absent a demonstration of criticality thereto.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '309 and '684 to provide aerosol corticosteroid particle formulations that meet the limitations of the instant claims based upon the motivation that corticosteroids are used in metered dose inhaler aerosol formulations for treatment of asthma and allergies and that the rate of dissolution of a particulate drug can increase with increasing surface area, i.e., decreasing particle size, along with providing optimal deposition with targeted sites within the respiratory tract.

5. Claims 35-36, 49, 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309) in view of Dalby et al (5,202,110; hereafter '110).

'309 is relied upon for all that it teaches as stated previously.

'110 is relied upon for teaching propellant metered dose inhalers where the propellant is a "non-CFC" propellant.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '309 with '110 to provide propellant metered dose inhalers where the propellant is a "non-CFC" propellant, thereby providing "environmentally friendly"

propellant compositions of the '309 compositions that provide distribution to the deep tissues of the lungs.

Response to Arguments

6. Applicant's arguments filed 10-15-02 have been fully considered but they are not persuasive. Applicants argue that the instant claims are allowable over Edwards et al ('309), arguing that '309 teaches techniques that result in amorphous drug. However, while the instant claims state inclusion of a poorly soluble crystalline drug, crystallinity does not appear to be a critical aspect of the instant claims. Both the instant claimed invention and that of '309 deliver the poorly soluble drugs. In fact, careful consideration of the instant specification shows that the compounds applicant intends to use in the instant invention are the same as those of '309. '309 administers these compounds in the same fashion (inhalation) to the deep tissues of the lungs and there accordingly does not appear to be any added benefit of the requirement where the drug is crystalline in the absence of a demonstration of criticality thereto. Applicant's comments that the claimed invention imparts useful benefits over the compositions of '309 on the basis of the teachings in the instant specification are deemed speculative and are not persuasive since the formulation of '309 is not compared in the specification.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Claims 120-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309) in view of Goodman and Gillman's (1996).

9. '309 is relied upon for all that it teaches as stated previously including aerosol administration of steroids.

10. Goodman and Gillman's teaches that beclomethasone dipropionate is known steroid administered for asthma in aerosol formulations.

11. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer beclomethasone dipropionate in the formulation of '309 with the motivation of providing a composition for treatment or asthma.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
December 20, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600